

Express Mail Label: EV074978638US  
Date of Deposit: May 15, 2002

05-16-07

Attorney Docket No.: 21402-015CIP (Curate-315CIP)

TECH CENTER 1600/2900

MAY 20 2002

RECEIVED  
#41645

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



APPLICANTS : Richard A. Shimkets  
SERIAL NUMBER : 09/994,228 EXAMINER : Not Yet Assigned  
FILING DATE : November 27, 2001 ART UNIT : 1645  
FOR : Nucleic Acids Containing Single Nucleotide Polymorphisms and Methods of Use Thereof

**BOX IDS**

Commissioner for Patents  
Washington, D.C. 20231

  
30623  
PATENT TRADEMARK OFFICE

**TRANSMITTAL LETTER**

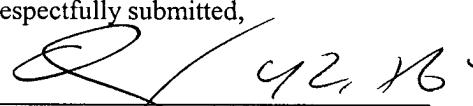
Transmitted herewith for filing in the present application are the following documents:

1. Information Disclosure Statement (2 pages), in duplicate;
2. Modified Form 1449/PTO (4 pages), in duplicate;
3. Copies of Cited References A1-A6, B1-B12 and C1-C71; and
4. Return Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 542-6000, Boston, Massachusetts.

The Commissioner is authorized to charge any fees that may be due, or to credit any overpayment, to the undersigned's account, Deposit Account No. 50-0311 Ref. No. 21402-015 CIP (Curate-315 CIP). A duplicate copy of this transmittal letter is enclosed herewith.

Respectfully submitted,

  
Ivor R. Elrifi, Reg. No. 39,529  
Attorney for Applicants  
MINTZ, LEVIN, COHN, FERRIS,  
GLOVSKY and POPEO, P.C.  
One Financial Center  
Boston, Massachusetts 02111  
Tel: (617) 542-6000  
Fax: (617) 542-2241

Dated: May 15, 2002

TRA 1666705v1



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Richard A. Shimkets  
SERIAL NUMBER: 09/994,228 EXAMINER: Not Yet Assigned  
FILING DATE: November 11, 2001 ART UNIT: 1645  
FOR: Nucleic Acids Containing Single Nucleotide Polymorphisms and Methods of Use  
Thereof

**BOX IDS**

Commissioner for Patents  
Washington, D.C. 20231

**INFORMATION DISCLOSURE STATEMENT**

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicants hereby make of record the documents listed on the attached modified Form PTO-1449, as well as copies of the listed documents.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits in the above-identified case. Accordingly, no fee or certification is believed required.

A copy of each of the references in the above-identified application is enclosed unless otherwise indicated on the attached modified Form PTO-1449. It is respectfully requested that the Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims, and signs the enclosed form PTO-1449 to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application.

By submitting this Information Disclosure Statement, the Applicants make no representation that: (1) a search has been performed, of the extent of any search performed, or that more relevant information does not exist; (2) the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b); and (3) the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

MAY 20 2002

TECH CENTER 1600/2900

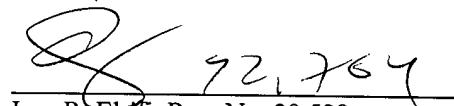
RECEIVED

APPLICANTS: Shimkets  
U.S.S.N.: 09/994,228

Notwithstanding any statements by the Applicants, the Examiner is urged to form his/her own conclusion regarding the relevance of the cited information. An early and favorable action is hereby requested.

Please charge any fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311, Reference No. 21402-015 CIP.

Respectfully submitted,



72,767

Ivor R. Elifii, Reg. No. 39,529  
Attorney for Applicants  
MINTZ, LEVIN, COHN, FERRIS,  
GLOVSKY and POPEO, P.C.  
One Financial Center  
Boston, Massachusetts 02111  
Tel: (617) 542-6000  
Fax: (617) 542-2241

Dated: May 15, 2002

TRA 1666700v1

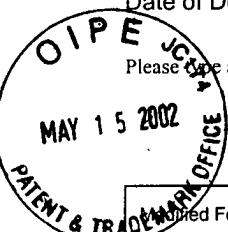
RECEIVED

Page 1 of 4  
MAY 20 2002

Express Mail No. EV074978638US

Date of Deposit: May 15, 2002

Please type a plus sign (+) in this box

+ 

TECH CENTER 1600/2000

PTO/SB (12-97)

Approved for use through 9/30/00. OMB 0651-0031

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Continued Form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	09/994,228
		Filing Date	11/27/2001
		First Named Inventor	Shimkets
		Group Art Unit	1645
		Examiner Name	Not Yet Assigned
		Attorney Docket Number	21402-015 CIP

## U.S. PATENT DOCUMENTS

Exam Initials	Cite No.	U.S. Patent Document No.	Issue Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date If Appropriate
	A1	4,683,202	07/28/87	Mullis			10/25/1985
	A2	5,292,639	03/08/94	Beitz, et al.			04/24/1992
	A3	4,511,503	04/16/85	Olson, et al.			06/01/1984
	A4	4,946,778	08/07/90	Ladner, et al.			01/19/1989
	A5	5,225,539	07/06/93	Winter			10/25/1991
	A6	4,816,567	03/28/89	Cabilly, et al.			03/08/1983

## FOREIGN PATENT DOCUMENTS

Exam Initials	Cite No.	Foreign Patent Document Office Number	Name of Patentee(s) or Applicant(s)	Date of Publication	Translation Yes No
	B1	EP 0 717 113	Affymax Technologies	06/19/1996	
	B2	EP 0 235 726	Molecular Diagnostics, Inc.	09/09/1987	
	B3	EP 0 184 187	Teijin Limited	06/11/1986	
	B4	EP 0 171 496	Research Development Corporation of JP	02/19/1986	
	B5	EP 0 173 494	Board of Trustees of the Leland Stanford University	03/05/1986	
	B6	EP 0 125 023	Genentech, Inc.	11/14/1984	
	B7	WO 97/29212	Affymetrix	08/14/1997	
	B8	WO 89/11548	Cetus Corporation	11/30/1989	
	B9	WO 95/11995	Affymax Technologies	05/04/1995	
	B10	WO 93/22456	Trustees of Dartmouth College	11/11/1993	
	B11	WO 95/12607	Molecular Tool, Inc.	05/11/1995	
	B12	WO 86/01533	Celltech Limited	03/13/1986	

## OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
	C1	Abravaya, et al. (1995). "Detection of point mutations with a modified ligase chain reaction (Gap- LCR)." <i>Nucleic Acids Res</i> 23(4): 675-82.
	C2	Barany (1991). "Genetic disease detection and DNA amplification using cloned thermostable ligase." <i>Proc Natl Acad Sci U S A</i> 88(1): 189-93.
	C3	Beggs (1978). "Transformation of yeast by a replicating hybrid plasmid." <i>Nature</i> 275(5676): 104-9.
	C4	Beidler, et al. (1988). "Cloning and high level expression of a chimeric antibody with specificity for human carcinoembryonic antigen." <i>J Immunol</i> 141(11): 4053-60.

Date of Deposit: May 15, 2002



TECH CENTER 1600/290

MAY 20 2002

RECEIVED

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS		
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
	C5	Benton and Davis (1977). "Screening lambda gt recombinant clones by hybridization to single plaques in situ." <i>Science</i> 196: 180-182.
	C6	Better, et al. (1988). "Escherichia coli secretion of an active chimeric antibody fragment." <i>Science</i> 240(4855): 1241-3.
	C7	Botstein, et al. (1979). "Sterile host yeasts (SHY): a eukaryotic system of biological containment for recombinant DNA experiments." <i>Gene</i> 8(1): 17-24.
	C8	Broach, et al. (1979). "Transformation in yeast: development of a hybrid cloning vector and isolation of the CAN1 gene." <i>Gene</i> 8(1): 121-33.
	C9	Capecci (1989). "Altering the genome by homologous recombination." <i>Science</i> 244: 1288-1292.
	C10	Carruthers (1981). "Recurrent melioidosis mimicking lung abscess." <i>Am Rev Respir Dis</i> 124(6): 756-8.
	C11	Collins (1992). "Positional cloning: let's not call it reverse anymore." <i>Nat Genet</i> 1(1): 3-6.
	C12	Cote, et al. (1983). "Generation of human monoclonal antibodies reactive with cellular antigens." <i>Proc. Natl. Acad. Sci. USA</i> 80: 2026-2030.
	C13	Cotton, et al. (1988). "Reactivity of cytosine and thymine in single-base-pair mismatches with hydroxylamine and osmium tetroxide and its application to the study of mutations." <i>Proc Natl Acad Sci U S A</i> 85(12): 4397-401.
	C14	Faham and Cox (1995). "A novel in vivo method to detect DNA sequence variation." <i>Genome Res</i> 5(5): 474-82.
	C15	Fahy, et al. (1991). "Self-sustained sequence replication (3SR): an isothermal transcription- based amplification system alternative to PCR." <i>PCR Methods Appl</i> 1(1): 25-33.
	C16	Fischer and Lerman (1983). "DNA fragments differing by single base-pair substitutions are separated in denaturing gradient gels: correspondence with melting theory." <i>Proc Natl Acad Sci U S A</i> 80(6): 1579-83.
	C17	Gautier, et al. (1987). "Alpha-DNA. IV: Alpha-anomeric and beta-anomeric tetrathymidylates covalently linked to intercalating oxazolopyridocarbazole. Synthesis, physicochemical properties and poly (rA) binding." <i>Nucleic Acids Res</i> 15(16): 6625-41.
	C18	Gibbs, et al. (1989). "Detection of single DNA base differences by competitive oligonucleotide priming." <i>Nucleic Acids Res</i> 17(7): 2437-48.
	C19	Grunstein and Hogness (1975). "Colony hybridization: a method for the isolation of cloned DNAs that contain a specific gene." <i>Proc Natl Acad Sci U S A</i> 72(10): 3961-5.
	C20	Gubler and Hoffman (1983). "A simple and very efficient method for generating cDNA libraries." <i>Gene</i> 25(2-3): 263-9.
	C21	Herskowitz and Hagen (1980). "The lysis-lysogeny decision of phage lambda: explicit programming and responsiveness." <i>Annu Rev Genet</i> 14: 399-445.
	C22	Hinnen, et al. (1978). "Transformation of yeast." <i>Proc Natl Acad Sci U S A</i> 75(4): 1929-33.
	C23	Huse, et al. (1989). "Generation of a large combinatorial library of the immunoglobulin repertoire in phage lambda [see comments]." <i>Science</i> 246(4935): 1275-81.
	C24	Inoue, et al. (1987). "Synthesis and hybridization studies on two complementary nona2-O-methylribonucleotides." <i>Nucl. Acids Res.</i> 15: 6131-6148.
	C25	Inoue, et al. (1987). "Sequence-dependent hydrolysis of RNA using modified oligonucleotide splints and RNase H." <i>FEBS Lett.</i> 215: 327-330.
	C26	Ito, et al. (1983). "Transformation of intact yeast cells treated with alkali cations." <i>J Bacteriol</i> 153(1): 163-8.
	C27	Kan and Dozy (1978). "Antenatal diagnosis of sickle-cell anaemia by D.N.A. analysis of amniotic-fluid cells." <i>Lancet</i> 2(8096): 910-2.
	C28	Kaufman (1990). "Selection and coamplification of heterologous genes in mammalian cells." <i>Methods Enzymol</i> 185: 537-66.
	C29	Kerem, et al. (1989). "Identification of the cystic fibrosis gene: genetic analysis." <i>Science</i> 245(4922): 1073-80.
	C30	Kohler and Milstein (1975). "Continuous cultures of fused cells secreting antibody of predefined specificity." <i>Nature</i> 256(5517): 495-7.
	C31	Kozbor and Roder (1983). "The production of monoclonal antibodies from human lymphocytes." <i>Immunology Today</i> 4(3): 72-79.
	C32	Kren, et al. (1999). "Correction of the UDP-glucuronosyltransferase gene defect in the Gunn rat model of crigler-najjar syndrome type I with a chimeric oligonucleotide." <i>Proc Natl Acad Sci U S A</i> 96(18): 10349-54.

TECH CENTER 1600  
 MAY 20 2002

RECEIVED

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS		
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
	C33	Landegren, et al. (1988). "A ligase-mediated gene detection technique." <i>Science</i> 241(4869): 1077-80.
	C34	Lander and Botstein (1986). "Strategies for studying heterogeneous genetic traits in humans by using a linkage map of restriction fragment length polymorphisms." <i>Proc Natl Acad Sci U S A</i> 83(19): 7353-7.
	C35	Lander and Green (1987). "Construction of multilocus genetic linkage maps in humans." <i>Proc Natl Acad Sci U S A</i> 84(8): 2363-7.
	C36	Liu, et al. (1987). "Chimeric mouse-human IgG1 antibody that can mediate lysis of cancer cells." <i>Proc Natl Acad Sci U S A</i> 84(10): 3439-43.
	C37	Liu, et al. (1987). "Production of a mouse-human chimeric monoclonal antibody to CD20 with potent Fc-dependent biologic activity." <i>J Immunol</i> 139(10): 3521-6.
	C38	Maskos and Southern (1993). "A novel method for the parallel analysis of multiple mutations in multiple samples." <i>Nucleic Acids Res</i> 21(9): 2269-70.
	C39	Mattila, et al. (1991). "Fidelity of DNA synthesis by the <i>Thermococcus litoralis</i> DNA polymerase-- an extremely heat stable enzyme with proofreading activity." <i>Nucleic Acids Res</i> 19(18): 4967-73.
	C40	Morrison (1985). "Transfectomas provide novel chimeric antibodies." <i>Science</i> 229(4719): 1202-7.
	C41	Myers, et al. (1985). "Detection of single base substitutions by ribonuclease cleavage at mismatches in RNA:DNA duplexes." <i>Science</i> 230(4731): 1242-6.
	C42	Needham-VanDevanter, et al. (1984). "Characterization of an adduct between CC-1065 and a defined oligodeoxynucleotide duplex." <i>Nucleic Acids Res</i> 12(15): 6159-68.
	C43	Needleman and Wunsch (1970). "A general method applicable to the search for similarities in the amino acid sequence of two proteins." <i>J Mol Biol</i> 48(3): 443-53.
	C44	Newton, et al. (1989). "Analysis of any point mutation in DNA. The amplification refractory mutation system (ARMS)." <i>Nucleic Acids Res</i> 17(7): 2503-16.
	C45	Nikiforov, et al. (1994). "Genetic Bit Analysis: a solid phase method for typing single nucleotide polymorphisms." <i>Nucleic Acids Res</i> 22(20): 4167-75.
	C46	Nishimura, et al. (1987). "Recombinant human-mouse chimeric monoclonal antibody specific for common acute lymphocytic leukemia antigen." <i>Cancer Res</i> 47(4): 999-1005.
	C47	Orita, et al. (1989). "Rapid and sensitive detection of point mutations and DNA polymorphisms using the polymerase chain reaction." <i>Genomics</i> 5(4): 874-9.
	C48	Orum, et al. (1993). "Single base pair mutation analysis by PNA directed PCR clamping." <i>Nucleic Acids Res</i> 21(23): 5332-6.
	C49	Pearson and Lipman (1988). "Improved tools for biological sequence comparison." <i>Proc Natl Acad Sci U S A</i> 85(8): 2444-8.
	C50	Queen, et al. (1986). "Cell-type specific regulation of a kappa immunoglobulin gene by promoter and enhancer elements." <i>Immunol Rev</i> 89: 49-68.
	C51	Rossiter and Caskey (1991). "Molecular studies of human genetic disease." <i>Faseb J</i> 5(1): 21-7.
	C52	Saiki, et al. (1986). "Analysis of enzymatically amplified beta-globin and HLA-DQ alpha DNA with allele-specific oligonucleotide probes." <i>Nature</i> 324(6093): 163-6.
	C53	Saiki, et al. (1988). "Primer-directed enzymatic amplification of DNA with a thermostable DNA polymerase." <i>Science</i> 239(4839): 487-91.
	C54	Saiki, et al. (1989). "Genetic analysis of amplified DNA with immobilized sequence-specific oligonucleotide probes." <i>Proc Natl Acad Sci U S A</i> 86(16): 6230-4.
	C55	Schneider (1972). "Cell lines derived from late embryonic stages of <i>Drosophila melanogaster</i> ." <i>J Embryol Exp Morphol</i> 27(2): 353-65.
	C56	Shaw, et al. (1988). "Mouse/human chimeric antibodies to a tumor-associated antigen: biologic activity of the four human IgG subclasses." <i>J Natl Cancer Inst</i> 80(19): 1553-9.
	C57	Smith (1968). "Linkage scores and corrections in simple two- and three-generation families." <i>Ann Hum Genet</i> 32(2): 127-50.
	C58	Sprague, et al. (1983). "Expression of a recombinant DNA gene coding for the vesicular stomatitis virus nucleocapsid protein." <i>J Virol</i> 45(2): 773-81.
	C59	Sun, et al. (1987). "Chimeric antibody with human constant regions and mouse variable regions directed against carcinoma-associated antigen 17-1A." <i>Proc Natl Acad Sci U S A</i> 84(1): 214-8.

TECH CENTER 6000/2900  
MAY 2002

MAY 2002

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS		
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
A	C60	Syvanen, et al. (1990). "A primer-guided nucleotide incorporation assay in the genotyping of apolipoprotein E." <i>Genomics</i> 8(4): 684-92.
	C61	Thiede, et al. (1996). "Simple and sensitive detection of mutations in the ras proto-oncogenes using PNA-mediated PCR clamping." <i>Nucleic Acids Res</i> 24(5): 983-4.
	C62	Verhoeven, et al. (1988). "Reshaping human antibodies: grafting an antilysozyme activity." <i>Science</i> 239(4847): 1534-6.
	C63	Wagner, et al. (1995). "Mutation detection using immobilized mismatch binding protein (MutS)." <i>Nucleic Acids Res</i> 23(19): 3944-8.
	C64	Wainwright (1993). "The isolation of disease genes by positional cloning." <i>Med J Aust</i> 159(3): 170-4.
	C65	Walker, et al. (1992). "Isothermal in vitro amplification of DNA by a restriction enzyme/DNA polymerase system." <i>Proc Natl Acad Sci U S A</i> 89(1): 392-6.
	C66	Wallace, et al. (1979). "Hybridization of synthetic oligodeoxyribonucleotides to phi chi 174 DNA: the effect of single base pair mismatch." <i>Nucleic Acids Res</i> 6(11): 3543-57.
	C67	Wood, et al. (1985). "The synthesis and in vivo assembly of functional antibodies in yeast." <i>Nature</i> 314(6010):446-9.
	C68	Wu and Wallace (1989). "The ligation amplification reaction (LAR)--amplification of specific DNA sequences using sequential rounds of template-dependent ligation." <i>Genomics</i> 4(4): 560-9.
	C69	Yamaoka, et al. (1990). "Tight linkage of creatine kinase (CKMM) to myotonic dystrophy on chromosome 19." <i>Neurology</i> 40(2): 222-6.
	C70	Yanofsky, et al. (1984). "Repression is relieved before attenuation in the trp operon of <i>Escherichia coli</i> as tryptophan starvation becomes increasingly severe." <i>J Bacteriol</i> 158(3): 1018-24.
	C71	Youil, et al. (1995). "Screening for mutations by enzyme mismatch cleavage with T4 endonuclease VII." <i>Proc Natl Acad Sci U S A</i> 92(1): 87-91.

\* a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. \_\_\_\_\_, filed \_\_\_\_\_, and relied upon for an earlier filing date under 35 U.S.C. §120 (continuation, continuation-in-part, and divisional applications).

Examiner Signature		Date Considered
--------------------	--	-----------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered.

Include copy of this form with next communication to applicant.

TRA 1666549v1